U.S. Department of Justice
Consumer Protection Branch

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August 31, 2022

VIA FEDEX AND EMAIL

Soul Vapor, LLC
604 Thorn Street
Princeton, WV 24740-3757
soulvaporejuice@gmail.com

Aurelius Jeffrey
816 Highland Ave., #5
Princeton, WV 24740
aureliusjeffrey@yahoo.com

Re: Violations of the Federal Food, Drug, and Cosmetic Act by Soul Vapor, LLC and Aurelius Jeffrey

Dear Mr. Jeffrey:

The United States Food and Drug Administration ("FDA") has advised the Department of Justice that you and Soul Vapor, LLC ("Soul Vapor") are in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"). The government is prepared to seek a permanent injunction against you and Soul Vapor to prevent further violations. I write to you in the hope of securing your timely compliance with the FDCA without litigation.

The lawsuit that FDA has requested is based upon your and Soul Vapor's repeated violations of the FDCA. Evidence collected by FDA establishes that you and Soul Vapor violate 21 U.S.C. § 331(k), by causing tobacco products to become adulterated and misbranded while they are held for sale after shipment of one or more of their components in interstate commerce. In addition, evidence collected by FDA establishes that you and Soul Vapor violated 21 U.S.C. § 331(q)(2) by submitting materially false information in your September 2021 establishment registration to FDA. The FDCA expressly provides for injunctive relief in federal district courts for such violations. *See* 21 U.S.C. § 332(a). We plan to seek a court order to permanently enjoin you and Soul Vapor from, among other things, directly or indirectly manufacturing, distributing, selling, and/or offering for sale any new tobacco product[1] at or from your facility, unless and

[1] "New tobacco product" refers to a tobacco product that meets the definition for such term at 21 U.S.C. § 387j(a)(1)—i.e., "any tobacco product (including those products in test

until, among other things, the product receives, and has in effect, marketing authorization from FDA.

The enclosed proposed consent decree states the terms upon which the government would be willing to settle the suit that we plan to file. I am communicating this offer of settlement directly to you because, to the best of my knowledge, you are not represented by counsel in connection with this matter. If you do have legal representation, please forward this correspondence to your attorney(s) and ask that they contact me. If you are not represented by counsel, please consider consulting with an attorney regarding this proposed settlement. I am sending this letter to Mr. Jeffrey in his personal capacity *and* as the owner of Soul Vapor. Because companies must be represented by counsel in federal court suits, Soul Vapor will need to be represented by an attorney for the purpose of executing the proposed consent decree, regardless of whether any individual decides to hire a personal attorney. Accordingly, please forward this proposal immediately to an attorney for Soul Vapor.

Please contact me, or have an attorney contact me, at ellen.bowden.mcintyre@usdoj.gov, no later than the close of business on September 8, 2022. Please also have an attorney for the company contact me. If I have not heard from you or your attorney by then, I will assume that you and Soul Vapor are not interested in resolving this matter. If that is the case, the Department of Justice will sue you and Soul Vapor in federal court seeking a permanent injunction against future violations.

Sincerely,

/s *Ellen Bowden McIntyre*

Trial Attorney
Consumer Protection Branch

Enclosure: Proposed Consent Decree

cc: William Thanhauser, FDA, OCC

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markets) that was not commercially marketed in the United States as of February 15, 2007" or "any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007." FDA has collected evidence that you and Soul Vapor manufacture finished electronic nicotine delivery system products, including finished e-liquids under the Soul Vapor brand, that were not commercially marketed in the United States as of February 15, 2007, and thus are "new tobacco products."